versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

ACCUTANE (isotretinoin) Capsules, 10 mg, 20 mg, and 40 mg, are the subject of NDA 18–662, held by Hoffman-La Roche, Inc. (Roche), and initially approved on May 7, 1982. ACCUTANE is indicated for the treatment of severe recalcitrant nodular acne. In a letter dated June 24, 2009, Roche notified FDA that ACCUTANE (isotretinoin) Capsules, 10 mg, 20 mg, and 40 mg, were being discontinued, and FDA moved the drug product to the "Discontinued Drug Product List" section of the Orange Book. There are three approved ANDAs for isotretinoin capsules; these are listed in the Orange Book and, following the discontinuation of ACCUTANE, one of them was designated as the listed drug to which new ANDAs should refer.

Sun Pharmaceutical Industries, Inc., submitted a citizen petition dated March 22, 2010 (Docket No. FDA–2010–P–0171), under 21 CFR 10.30, requesting that the agency determine whether ACCUTANE (isotretinoin) Capsules, 10 mg, 20 mg, and 40 mg, were withdrawn from sale for reasons of safety or effectiveness.

FDA has reviewed its records and, under § 314.161, has determined that ACCUTANE (isotretinoin) Capsules, 10 mg, 20 mg, and 40 mg, were not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that ACCUTANE (isotretinoin) Capsules, 10 mg, 20 mg, and 40 mg, were withdrawn for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse events and has found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list ACCUTANE (isotretinoin) Capsules, 10 mg, 20 mg, and 40 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

FDA will not begin procedures to withdraw approval of approved ANDAs that refer to ACCUTANE. Additional ANDAs for isotretinoin capsules may also be approved by the agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for isotretinoin capsules should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: June 30, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–16439 Filed 7–6–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES≤

Food and Drug Administration

[Docket Nos. FDA–2010–P–0027, FDA–2010–P–0059, and FDA–2010–P–0051]

Determination That ACTONEL (Risendronate Sodium) Tablets, 75 Milligrams, and ACTONEL WITH CALCIUM (Risendronate Sodium and Calcium Carbonate (Copackaged)) Tablets, 35 Milligrams/500 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the determination that ACTONEL (risendronate sodium) Tablets, 75 milligrams (mg), and ACTONEL WITH CALCIUM (risendronate sodium and calcium carbonate (copackaged)) Tablets, 35 mg/500 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for these products, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Jane Baluss, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6362, Silver Spring, MD 20993–0002, 301–796–3469.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an

ANDA that does not refer to a listed drug.

Lachman Consultant Services submitted a petition dated January 12, 2010 (FDA–2010–P–0027), requesting a determination that ACTONEL (risendronate sodium) Tablets, 75 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. ACTONEL (risendronate sodium) Tablets, 75 mg, is the subject of NDA 20–835, held by Warner Chilcott and initially approved on April 16, 2004. ACTONEL (risendronate sodium) Tablets, 75 mg, is indicated for the treatment of postmenopausal osteoporosis in men, and Paget's disease in men and women.

In a separate citizen petition dated January 20, 2010 (FDA–2010–P–0051), Lachman Consultant Services requested a determination that ACTONEL WITH CALCIUM (risendronate sodium and calcium carbonate (copackaged)) Tablets, 35/500 mg, was not withdrawn from sale for reasons of safety or effectiveness. In another separate petition dated January 21, 2010, EAS Consulting Group, LLC, requested the same determination on behalf of Aurobindo Pharmaceuticals. ACTONEL WITH CALCIUM (risendronate sodium and calcium carbonate (copackaged)) Tablets, 35/500 mg, is the subject of NDA 21–823, held by Procter & Gamble and initially approved on August 12, 2005. ACTONEL WITH CALCIUM (risendronate sodium and calcium carbonate (copackaged)) Tablets, 35/500 mg, is indicated for the treatment of postmenopausal osteoporosis.

FDA has reviewed its records and, under § 314.161, has determined that neither ACTONEL (risendronate sodium) Tablets, 75 mg, nor ACTONEL WITH CALCIUM (risendronate sodium and calcium carbonate (copackaged)) Tablets, 35/500 mg, was withdrawn from sale for reasons of safety or effectiveness. None of the petitions identified any data or other information suggesting that either of the products named in the petitions was withdrawn for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse events and has found no information that would indicate that either product was withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list ACTONEL (risendronate sodium) Tablets, 75 mg, and ACTONEL WITH CALCIUM (risendronate sodium and calcium carbonate (copackaged)) Tablets, 35/500 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

ANDAs that refer to ACTONEL (risendronate sodium) Tablets, 75 mg, or ACTONEL WITH CALCIUM (risendronate sodium and calcium carbonate (copackaged)) Tablets, 35/500 mg, may be approved by the agency if all other legal and regulatory requirements for the approval of ANDAs are met. If FDA determines that labeling for either or both of these drug products should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: June 30, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–16438 Filed 7–6–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES≤

Food and Drug Administration

[Docket No. FDA–2010–N–0298]

Disclosure of Nutrient Content Information for Standard Menu Items Offered for Sale at Chain Restaurants or Similar Retail Food Establishments and for Articles of Food Sold From Vending Machines

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments, data, and information.

SUMMARY: The Food and Drug Administration (FDA) is announcing the opening of a docket to solicit comments, data, and other information helpful to the implementation of section 4205 of the Patient Protection and Affordable Care Act of 2010, which was enacted on March 23, 2010. That section, principally amending sections 403 and 403A of the Federal Food, Drug, and Cosmetic Act (the act), requires chain restaurants and similar retail food establishments with 20 or more locations doing business under the same name and offering for sale substantially the same menu items to disclose nutrient content information for standard menu items appearing on restaurant menus and menu boards, and requires vending machine operators that own or operate 20 or more vending machines to disclose nutrient content information for certain articles of food sold from vending machines. Section 4205 also amended the act to allow restaurants or similar retail food establishments and operators of vending machines not subject to the requirements of section 4205 to elect to be subject to the requirements through biannual registration. FDA is establishing this docket to provide an opportunity for interested parties to submit data and other information relevant to the implementation of section 4205.

DATES: Submit either electronic or written comments by September 7, 2010.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Geraldine A. June, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy, College Park, MD 20740, 301–436–2371.

SUPPLEMENTARY INFORMATION:

I. Background

The availability of nutritional information through menu labeling would provide Americans the opportunity to exercise personal responsibility and make informed choices about their diets. Studies show that providing nutrition information at restaurants can help people make healthier choices (e.g., Refs. 1 and 2). Responding to this demand for information, several states and localities have initiated legislative or regulatory efforts on restaurant menu labeling, creating a patchwork of ideas and logistical challenges for many restaurant chains (Ref. 3). While various approaches to menu labeling in chain restaurants have been tried, several stakeholders ultimately sought a national approach that would ensure nationwide uniformity, better protections, and flexibility in how additional nutrition information is provided.

On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act (Affordable Care Act) (Public Law 111–148). Section 4205 of the Affordable Care Act (hereinafter "section 4205") creates a new subparagraph (H) within section 403(q)(5) of the Federal Food, Drug, and Cosmetic Act (the act), to be codified at 21 U.S.C. 343(q)(5)(H), which requires chain restaurants and similar retail food establishments with 20 or more locations doing business under the same name and offering for sale substantially